510(k) SUMMARY

OLYMPUS XCYF-1T3

OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer: Olympus Optical Co., Ltd.
22-2 Nishi-Shinjuku, 1-Chome,
Shinjuku-ku, Tokyo 163-8610
Japan

Registration No: 8010047

Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,
Hachioji-shi, Tokyo 192-8507, Japan
R&D Department, Endoscope Division
Tel: 81-426-42-5101
Fax: 81-426-46-2786

B. Name of Contact Person

Tadahiko Ogasawara

K 993041
pg 2 of 3

C. Trade Name, Common Name, Classification Number, Classification

Trade Name :	Olympus XCYF - 1T3 OES Cystofiberscope/Nephrofiberscope Accessories and Ancillary Equipment
Common Name:	Cystofiberscope/Nephrofiberscope
Classification Number:	21 CFR 876.1500 Endoscopes and Accessories
Predicate Device Classification :	K843084 Olympus Nephroscope/Cystoscope K904940 Infant Resectoscope & Accessories

D. Description of the Device

The Olympus XCYF-1T3 OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE has been specifically designed to be used with an Olympus Light Source, documentation, equipment, and display monitor. The XCYF-1T3 is equipped with a large Instrument Channel of bright optical quality compared to the

predicate device, XCYF-1T3. These characteristics facilitate operation under endoscopic-surgery including high-frequency treatment within the bladder, urethra and kidney.

E. Intended Use of the Device(s)

The Olympus XCYF-1T3 OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE, accessories and ancillary equipment have been specifically designed to be used in endoscopic diagnosis and treatment within the bladder, urethra and kidney. Do not use these instruments for any purpose other than their intended use.

F. General Safety

The Olympus XCYF-1T3 OES Cystofiberscope/Nephrofiberscope is manufactured and tested according to voluntary safety standards IEC60601-1 and IEC60601-2-18. XCYF-1T3 is designed for electrosurgical treatment within the bladder, urethra and kidney. When compared to the predicate device, the Olympus Nephroscope/Cystoscope Model CHF-P10, except for the electrosurgical treatment, does not incorporate any significant change in operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2000

The Olympus Optical Company
c/o Robert Schiff, Ph.D., RAC, CQA (ASQC)
President
Schiff & Company
1129 Bloomfield Avenue
West Caldwell, NJ 07006

Re: K993041
Olympus XCYF-1T3 OES
Cystofiberscope/Nephrofiberscope
Dated: March 14, 2000
Received: March 15, 2000
Regulatory Class: I
21 CFR §876.1500/Procode: 78 FCL
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FAJ, FGA, KOG
21 CFR §876.4300/Procode: 78 FDI, KGE, KNS

Dear Dr. Schiff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

K993041

OLYMPUS

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not assigned yet

Device Name: Oiympus XCYF-1 T3 OES CYSTOFIBESCOPE/ NEPHROFIBERSCOPE, accessories and ancillary equipment.

Indications for Use:

These instruments have been designed to be used with an Olympus Light Source, Documentation Equipment, Display Monitor, Suction Pump, Endo-Therapy Accessories, elecrosurgical Unit, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidneys.

Do not use this instrument for any purpose other than its intended use.

(PLEASE DO NOT WRITE BELLOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFER 801. 109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993041

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